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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,113	10/30/2001	Grant L. Schoenhard	PAIN-003/03US	8969

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EXAMINER

JARVIS, WILLIAM R A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 03/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/000,113

Applicant(s)

SCHOENHARD, GRANT L.

Examiner

William R. Jarvis

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-393 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-393 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

*Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-44, drawn to a method of enhancing efficacy of a non-opioid CNS-active agent by administering a non-opioid CNS active agent and an amount of an inhibitor of a drug transporter, classified in class 514, subclass 282 *et al.*
  - II. Claims 45-66 and 165-186, drawn to a method of reversing tolerance to a non-opioid CNS-active agent by administering an inhibitor of a drug transporter and a non-opioid CNS-active agent, classified in class 514, subclass 282 *et al.*
  - III. Claims 67-164, drawn to a method of treating a patient with chronic pain by coadministering a non-opioid CNS-active agent and an inhibitor of a drug transporter, classified in class 514, subclass 282 *et al.*
  - IV. Claims 187 and 188, drawn to a method of inhibiting a P-glycoprotein by administering a P-glycoprotein inhibiting amount of an ABC drug transporter and a non-opioid CNS-active agent, classified in class 514, subclass 282 *et al.*
  - V. Claims 189-228, drawn to a method of enhancing efficacy of an opioid CNS-active agent by administering an opioid CNS active agent and an amount of an inhibitor of a drug transporter, classified in class 514, subclass 282 *et al.*
  - VI. Claims 229-248 and 339-360, drawn to a method of reversing tolerance to an opioid CNS-active agent by administering an inhibitor of a drug transporter and an opioid CNS-active agent, classified in class 514, subclass 282 *et al.*
  - VII. Claims 249-338, drawn to a method of treating a patient with chronic pain by coadministering an opioid CNS-active agent and an inhibitor of a drug transporter, classified in class 514, subclass 282 *et al.*
  - VIII. Claims 361 and 370-372, drawn to a composition comprising an opioid receptor agonist and a non-opioid compound, classified in class 514, subclass 282 *et al.*
  - IX. Claims 362-369 and 373-376, drawn to a composition comprising a non-opioid CNS active agent and an opioid receptor antagonist, classified in class 514, subclass 282 *et al.*

- X. Claims 377-393, drawn to methods for identifying a compound suitable for coadministration with a CNS-active agent for enhanced efficacy of the CNS-active agent, for identifying a compound as a therapeutic agent for transport across the blood-brain barrier, and for enhancing the potency of said compound classified in class 424, various subclasses.

The inventions are distinct, each from the other because they relate to different processes involving different types of compounds (e.g. opioid and non-opioid CNS active agents), which have different functions and effects on the host. Furthermore, a reference anticipating or making obvious one invention alone would not anticipate or make obvious the invention of another group. In addition, it is clearly burdensome for the examiner to search and examine 393 claims in one application.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
3. Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. Claims 1-376 are generic to a plurality of disclosed patentably distinct species comprising (1) various non-opioid CNS-active agents or opioid CNS-active agents, as well as (2) inhibitors of ABC drug transporters. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from both (1) and (2), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

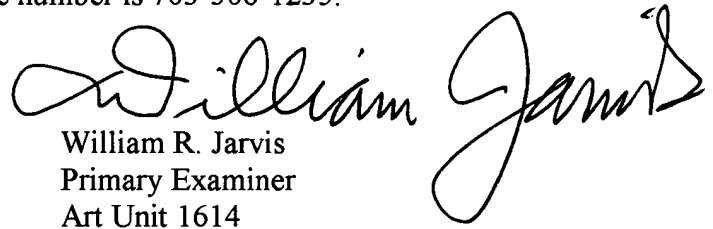
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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
William R. Jarvis  
Primary Examiner  
Art Unit 1614

wrj  
March 2, 2003